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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,946	08/22/2001	Charles Chauveau	C1190/20008	5350

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/830,946	Applicant(s) CHAUVEAU ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for Continued Examination, Amendment D, and Information Disclosure received December 2, 2002 are acknowledged. Claims 48-74 are included in the prosecution of this application. Claims 21-47 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "said active principle not being intimately dispersed or dissolved in a pharmaceutically acceptable lipid" does not have support in the specification. If this is not new matter, applicant is requested to clearly point support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60 and 74 recites the limitation "sweetener" in claim 50 and 63 respectively. There is insufficient antecedent basis for this limitation in the claim since the claims it is depending from does not recite "the sweetener". If this is typographical

error in which claim 60 is dependent on claim 49 and claim 74 is dependent on 62, appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 48-50, 53, 55-56, 59-63, 65, 67-70, and 73-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Gowan (5,876,759).

Gowan discloses a rapidly disintegrating tablet (30 seconds or less) containing coated acetaminophen (23%), mannitol (57%), microcrystalline cellulose (15%), aspartame, colloidal silicon dioxide (.06%), and stearic acid (.75%). Gowan teaches the particle size of the coated active and other components are generally less than 400 microns. Note examples.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 48-53, 55-57, 59-67, 69-71, and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gowan (5,876,759).

Although, Gowan anticipates instant invention, Gowan is also used in an obviousness rejection over the ranges since Gowan clearly teaches suitable ranges of all components; therefore one of ordinary skill would look at Gowan for guidance to provide for a rapidly disintegrating tablet. Gowan teaches a rapidly disintegrating tablet (30 seconds or less). The coated active such as aspirin and ibuprofen is contained in the amount of .1-45%, the water-disintegratable carbohydrate material such as mannitol and xylitol is contained in the amount 30-90%, the binder in the amount of 1-30%, and lubricant in the amount of .1-5% (magnesium stearate or talc), and colloidal silicon dioxide (examples, col. 6, and claims). Gowan teaches the inclusion of various excipients such as sweeteners (aspartame) (col. 6). Gowan teaches the particle size of the coated active and other components are generally less than 400 microns.

Gowan does not teach certain instant ranges.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the ranges taught by Gowan et al since Gowan provides

suitable ranges for instant components and it is readily apparent to one of ordinary skill to modify individual components within prior art conditions. One would be motivated to do so for routine optimization with the expectation of similar results.

Claims 54, 56-57, 68, 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gowan (5,876,759) in view of Ku et al (5,994,348).

As set forth above, Gowan teaches a rapidly disintegrating tablet.

Gowan does not teach instant disintegrant. Secondly, Gowan does not teach the instant range of silicon dioxide.

Ku et al teach a pharmaceutical composition with excellent wetting, disintegration, and rapid release properties (col. 2, lines 5-15). Ku teaches disintegrant such as microcrystalline cellulose or instant crospovidone or croscarmellose in instant amounts as agents that facilitate the break up of a tablet when the composition is placed in contact with an aqueous medium (col. 4, lines 1-20). Further, Ku teaches the use of anti-adherents such as .25-5% silicon dioxide. (col. 4, lines 20-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Ku et al since Ku teaches rapidly disintegrating tablets with similar excipients for rapid dissolution. Further, one would be motivated to do so since Ku teaches the equivalency of Gowan's microcrystalline cellulose and instant disintegrants. Therefore, one would reasonably expect similar results substituting the instant disintegrants since these are conventional disintegrants in the art as taught by Ku. Lastly, Ku provides the preferable range of silicon dioxide to provide for an anti-adherent effect.

Claims 48-52, 54-59, 61-66, and 68-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al (6,465,009).

Liu et al teach a rapidly disintegrating tablet in about 1 to 40 seconds (col. 2, lines 45-51). Liu teaches a formulation containing a coated active (up to 50%; exemplified 8.7%), a binder (.5-5%), at least one lubricant (.5-1%), and fillers (mannitol) (40-99%) (col. 3, lines 5-15, col. 7, lines 5-20, examples). Liu et al teaches croscarmellose sodium may be included as an additional disintegrant (col. 7, lines 64-68).

Liu et al does not teach inclusion of a permeabilizing agent.

Ku et al teach a pharmaceutical composition with excellent wetting, disintegration, and rapid release properties (col. 2, lines 5-15). Ku teaches the use of anti-adherents such as .25-5% silicon dioxide. (col. 4, lines 20-30). Further, Ku teaches the combination of magnesium stearate and silicon dioxide provides a superior lubrication effect while minimizing any decline in tablet dissolution performance (col. 5, lines 59-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Ku et al and include silicon dioxide in the composition since Ku teaches a rapidly disintegrating tablets with similar excipients for rapid dissolution. One would be motivated to do so since Ku teaches the advantages of using an anti-adherent agent in reducing the stickiness of the composition. Further, one would expect similar results since Ku teaches the combination of magnesium stearate, used by Liu, and silicon dioxide provide for an excellent lubricating effect.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

February 4, 2003

MICHAEL G. HARTLEY
PRIMARY EXAMINER